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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF POLLUTION PREVENTION AND TOXICS

REGULATION OF NEW CHEMICAL SUBSTANCES

PENDING DEVELOPMENT OF INFORMATION

In the matter of:	)	Premanufacture Notice Numbers:
	)	
	)	
	)	
	)	
	)	
[ ]	)	P-06-388, P-06-389 and P-06-390
	)	
	)	
	)	EPA SANITIZED
	)	
	)	

Consent Order and Determinations Supporting Consent Order

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I. INTRODUCTION

Under the authority of § 5(e) of the Toxic Substances Control Act ("TSCA") (15 U.S.C. 2604(e)), the Environmental Protection Agency ("EPA" or "the Agency") issues the attached Order, regarding premanufacture notices ("PMNs") P-06-388, P-06-389, and P-06-390 submitted by [.] ("the Company"), to take effect upon expiration of the PMN review period.

Under § 15 of TSCA, it is unlawful for any person to fail or refuse to comply with any provision of § 5 or any order issued under § 5. Violators may be subject to various penalties and to both criminal and civil liability pursuant to § 16, and to specific enforcement and seizure pursuant to § 17. In addition, chemical substances subject to an Order issued under § 5 of TSCA, such as this one, are subject to the § 12(b) export notice requirement.

II. SUMMARY OF TERMS OF THE ORDER

The Consent Order for these PMN substances requires the Company to:

(a) submit to EPA certain environmental fate and physical/chemical testing on P-06-390 at least 14 weeks before manufacturing or importing a total of [ ] kilograms of all three PMN substances combined; and

(b) maintain certain records.

III. CONTENTS OF PMN

Confidential Business Information Claims (Bracketed in the Preamble and Order): company identity, specific chemical identities, production volumes, manufacturing process, processing, and use information, and other information

Chemical Identities:

Specific: **P-06-388**-- [ ]; CAS Registry Number: [ ];

P-06-389–[ ]; CAS Registry Number: [ ]; and

P-06-390-- [ ];

CAS Registry Number: [ ].

Generic: **P-06–388, 389, 390**–perfluoroalkyl ethyl methacrylate copolymer

Use:

Specific: **P-06-388**: [ ]; **P-06-389**: [ ]; **P-06-390**: [ ]

Generic: **P-06-388**: textile treatment; **P-06-389**: textile/structural material treatment; **P-06-390**: textile treatment

Maximum 12-Month Production Volume: **P-06-388**: [ ] kgs; **P-06-389**: [ ] kgs; and

P-06-390: [ ] kgs

Test Data Submitted with PMNs (many acronyms are subsequently explained in section IV below):

Previously submitted relevant testing:

Submitted in December 2004:

1) Bioconcentration study of [ ] in carp; 2) Biodegradation study of [ ] by microorganisms; C6-2AL: 3) Acute Oral Toxicity in the rat; C6-2AL: 4) Reverse Mutation Study.

Submitted in 2005:

1) Perfluorohexanoic acid (PFHxA, PFHA) and the C6-2 Alcohol Combined Repeated Dose Toxicity Study with Reproduction/Developmental Screening test (OECD 422);

2) PFHxA: Pharmacokinetic (in Blood) and Excretion Study in Cynomolgus Monkeys of Perfluorohexanoic acid and Nonafluoro-1-butanesulfonic acid and later another study in 3) rats; 4) PFHA: Acute Toxicity to Daphnia magna; 5) PFHA: Acute Toxicity to Rainbow trout; 6) PFHA: Algal inhibition test; 7) Martin J., Mabury S. et al, Bioconcentration and Tissue Distribution Perfluorinated Acids in Rainbow Trout, Env. Toxicology and Chemistry vol. 22, no. 1 pp.196-204. C6-2 alcohol: 8) C6-2AL: Acute Toxicity to Daphnia Magna; 9) Acute Toxicity to Rainbow Trout; 10) Algal Inhibition Test; 11) Bioconcentration Study of C6-2 Alcohol in Carp;

Submitted in 2006:

1) A 90-day Repeated Dose Oral (gavage) Toxicity Study of Perfluorohexanoic Acid (PFHxA) in Rats (with Functional Observational Battery and Motor Activity Determinations)

IV. EPA'S ASSESSMENT OF EXPOSURE AND RISK

The following are EPA's predictions regarding the probable toxicity, human exposure and environmental release of the PMN substances, based on the information currently available to the Agency.

Human Health Effects and Fate Summary: EPA has concerns for potential incineration or other decomposition products of the PMN substances. EPA also has concerns that the PMN substances themselves under some conditions of use-- particularly non-industrial, commercial, or consumer use-- could cause lung effects, based on limited data on some perfluorinated compounds.

EPA has concerns for the potential degradation of these polymers and for the subsequent perfluorinated products. The PMN substances are derivatives of perfluorohexanoic acid, PFHxA or PFHA. Based on information submitted to EPA during the PMN review period, these substances have little or no higher chain length perfluorinated components or impurities due to their manufacturing process. There appear to be no C8 or higher homologs perfluorinated impurities and the C6 perfluorinated monomers/feedstock residuals are minimized and quantified based on submitted Certificates of Analysis and other information. In addition, the substances are made in a facility that is dedicated to the production of substances with C6 chemistry.

These perfluorinated products may be released to the environment from incomplete incineration of the PMN substances at low temperatures. Preliminary evidence, including data on similar PMN substances, suggests that, under some conditions, the PMN substances could degrade in the environment. EPA has concerns that these degradation products will persist in the environment, could bioaccumulate or biomagnify, and could be toxic (PBT) to people, wild

mammals, and birds based on data on analog chemicals, including perfluorooctanoic acid (PFOA) and perfluorohexane sulfonate (PFHxS). The presumed perfluorinated degradants for these PMN substances includes perfluorohexanoic acid, PFHxA. There is limited toxicological data in animals on PFHxA or precursors, which is summarized below.

PFOA is expected to persist for years in the environment. Biodegradation and photolysis tests of analogous substances indicate little or no biodegradation or photolysis of perfluoroalkyl compounds. Bioaccumulation concerns are based on the measured presence of certain perfluoroalkyl compounds, including PFOA, in wildlife and in human blood samples. Toxicity studies on PFOA indicate developmental, reproductive and systemic toxicity in various species. Cancer may also be of concern. These factors, taken together, raise concerns for potential adverse chronic effects in humans and wildlife. For additional information about PFOA consult the docket OPPT-2003-13. Additional information about PFOA, PFHxS, and other perfluorinated substances may also be found in the *Administrative Record for PFOS, PFOA, and Telomers and Related Chemicals (AR-226).*

Limited toxicological, ecological, and fate data now exist on PFHxA and some of the PFHxA-derived polymers and other substances; see the PMN docket for data for these specific PMNs. A pharmacokinetics study on PFHxA and for comparison perfluorobutane sulfonate (PFBS) in the Cynomolgus Monkey was submitted previously. This study indicates that the serum half-life of PFHxA in these monkeys is less than 24 hours, whereas the half-life of PFOA in monkeys is 20.9 days in female monkeys, 32.6 days in male monkeys, and 4.4 years in humans. The Company also conducted a pharmacokinetics study on PFHxA in rats that showed

a serum half-life of one hour or less. These data and assessments support the assessment of reduced bioaccumulation of PFHxA relative to PFOA.

In addition, the Company conducted a Combined Repeated-Dose Toxicity Study with Reproduction/Developmental Screening Test, (OECD 422) in rats for PFHxA and the C6-2 Alcohol. The EPA review of these subchronic and reproductive data on PFHxA and the C6 alcohol concluded that for PFHxA no reproductive effects were seen at any dose. Dose levels were 50, 150, and 450/300 mg/kg/day (450 was reduced to 300 in study on day 4 because of toxicity). However, systemic effects–primarily liver effects-- were seen. EPA review places the No-Adverse Effect Level or NOAEL for PFHxA at 50 mg/kg/day. For the C6 alcohol, the doses were 25, 75, and 225 mg/kg/day. For systemic effects, there was no NOAEL achieved with the Lowest-Adverse Effect Level (LOAEL) at 25 mg/kg/day. For reproductive or developmental effects, the NOAEL is 75 mg/kg/day and the LOAEL is 225 mg/kg/day.

In 2006, the Company submitted a 90-day oral repeated dose toxicity study (OECD 408). Dose levels for this study were 0 (vehicle control), 10, 50, or 200 mg/kg/day and were based on the previous Combined Study (OECD 422). EPA review sets the LOEL or LOAEL at 10 mg/kg/day based on the body weight gain being lower in all treated groups of males. There was treatment-related toxicity in the liver and the red blood cell system (anemia) in males at 200 mg/kg/day. There was also increased peroxisomal beta oxidation activity at this dose level. Hepaptotoxicity and peroxisomal beta oxidation activity have also been seen in studies on PFOA. The significance of the finding of a benign brain tumor (astrocytoma) in one male rat in the high dose group is not clear. It is not the type of tumor normally associated with PFOA-type compounds, is not a rare tumor, and may be incidental. Abnormal histopathology was observed

in the testes (2 males) and epididymides (1 male) at 200 mg/kg/day and is a sign of concern for male reproductive toxicity. Further testing should investigate male reproductive effects. From this study, the potential for immunotoxic effects is low. There have been some studies showing immunotoxic effects from PFOA. Any investigation of immunotoxic effects should await the corroborative testing now being conducted by EPA, Office of Research and Development. There were no clinical signs of neurotoxicity and there were no treatment-related effects in the functional observation battery or motor behavior.

These and other data indicate a different and less toxic profile for PFHxA, (a presumed environmental degradant of the PMN substances), in the data to date than for PFOA. Based on: 1) the persistence of PFHxA; 2) potential intermediate fate products; and, 3) the possibility or likelihood that these substances may be used as major substitutes for some uses of PFOA, EPA believes that more information is needed on the toxicity of PFHxA and possibly other environmental degradants and the fate, and physical/chemical properties of PFHxA-derived polymers in the environment.

EPA also believes that additional reproductive and long-term toxicological testing on PFHxA in animals is warranted. To this end, the Company has agreed to conduct a modified 1-generation reproductive test in rats (OECD 421, modified); and a two-year chronic toxicity/carcinogenicity test in rats (OECD 453). The modifications for the reproductive test include (1) increase the parental sample size to 20, (2) the duration of the study should be extended to until the pups have reached sexual maturation, (3) parental males should be dosed for 10 weeks prior to mating; (4) dosing of the parental animals should be continued through lactation and then the pups should be directly dosed until they reach sexual maturation, (5) pup

body weight should be recorded on lactation days 0, 4, 7, 14, and 21 and then at weekly intervals, (6) litter size can be standardized to 4 pups/litter on lactation day 4 (optional), (7) at weaning one pup/sex/litter can be randomly selected to follow until sexual maturation, and (8) the time of sexual maturation should be recorded (i.e. vaginal opening and preputial separation). An avian reproduction test (OECD 206) will also be conducted by the Company. In addition, comparative data, especially on the pharmacokinetics of PFHxA and other perfluorinated substances will be developed by testing of the National Toxicology Program (NTP) in the so-called Perfluoro Class Study.

Environmental Effects Summary: EPA expects the PMN substances to be highly persistent. No ecotoxicological concerns were raised for the PMN polymers themselves. However, there is high concern for possible environmental effects from the potential persistent degradation product PFHxA. As stated previously, the analog PFOA is persistent in the environment and has a long bioretention time in various species. It has been detected in a number of species of wildlife, including marine mammals. It is toxic to mammalian and other species. The presence in the environment and toxicological properties of PFOA continue to be investigated. Some limited acute ecotoxicological effects data exist on PFHxA in fish, daphnia, and algae. EPA believes development of additional data is warranted and the Company has agreed to conduct an Avian Reproduction Test (OECD 206) on PFHxA.

Exposure and Environmental Release Summary: Thermal and simulated incineration testing exists on some related polymers. This testing indicates that incomplete incineration products are

formed at lower incineration temperatures. Modified Zahn-Wellens biodegradation tests have been conducted on some related polymers. EPA has determined that the structurally analogous polymer degrades.

These PMN substances will be imported and used as [

]. These new chemicals are intended to be used in [ ] settings only.

In the processing of the PMN substances for use in [ ]: it is estimated that the substances could be used at 20 unknown [ ] sites for 250 days/per year. The PMN substances will be imported as a liquid at 20% concentration. The liquid will be mixed with other additives to a 0.1-2% concentration during use as a [

]. Release to water from equipment cleaning is estimated at up to 23 kg/site/day (of each chemical) over 250 days per year, although the media of release is uncertain. The waste could be incinerated or landfilled. In addition, release to water from container residue is estimated at 12 kg/site/day for 60 days/year. Again, it could also be incinerated or landfilled. If incinerated, some releases of the perfluoro component are expected.

An estimate of 120 workers could be exposed over 250 days annually. Inhalation is expected to be negligible, with dermal exposures estimated at 1800 mg/day. From use on textiles, it is expected that there is a possibility of release of the perfluoro component from the textile materials. If the substances are used on [

]. Exposure could also occur during [

]. The substances are intended to be applied at the factory for [

] uses and at the dye works or textile finishers to treat cloth. EPA expects that use on textiles could result in the environmental release of degradants of concern from low temperature incineration or burning.

V. EPA'S CONCLUSIONS OF LAW

The following findings constitute the basis of the Consent Order:

A. EPA is unable to determine the potential for human health and environmental effects from exposure to the PMN substances and potential degradation products. EPA therefore concludes, pursuant to § 5(e)(1)(A)(i) of TSCA, that the information available to the Agency is insufficient to permit a reasoned evaluation of the human health and environmental effects of the PMN substances and potential degradation products.

B. In light of the potential risk of human health and environmental effects posed by the uncontrolled manufacture, import, processing, distribution in commerce, use, and disposal of the PMN substances, and the Agency's conclusion that issuing the Order will not result in any significant loss of benefits to society, EPA has concluded, pursuant to § 5(e)(1)(A)(ii)(I) of TSCA, that uncontrolled manufacture, import, processing, distribution in commerce, use, and disposal of the PMN substance may present an unreasonable risk of injury to human health and the environment.

C. In light of the estimated production volume of, and human exposure to, the PMN substances and potential degradation products, EPA has further concluded, pursuant to § 5(e)(1)(A)(ii)(II) of TSCA, that the PMN substances will be produced in substantial quantities and may reasonably be

anticipated to enter the environment in substantial quantities, and there may be significant (or substantial) human exposure to the substance and potential degradation products.

VI. INFORMATION REQUIRED TO EVALUATE HUMAN HEALTH AND ENVIRONMENTAL EFFECTS

Triggered Testing. The Order prohibits the Company from exceeding a specified production volume unless the Company submits the information described in the Testing section of this Order in accordance with the conditions specified in the Testing section.

Pending Testing. The Order does not require submission of the following information at any specified time or production volume. However, the Order's restrictions on manufacture, import, processing, distribution in commerce, use, and disposal of the PMN substances will remain in effect until the Order is modified or revoked by EPA based on submission of the following or other relevant information.

1. Because some concerns for the PMN substances are based on analogy between PFHxA and PFOA, and because PFHxA is a potential ultimate degradation product of the PMN substances, the following additional information on PFHxA would be necessary to evaluate the human health and environmental effects which may be caused by the PMN substances: a modified 1-generation reproduction study in rats (OECD Guideline 421 modified as stated earlier in the Preamble); a combined chronic toxicity/carcinogenicity test (OECD Guideline 453); and an avian reproduction test (OECD Guideline 206). The Company has agreed to perform this testing. For the new animal toxicity testing, the Company has agreed to submit protocols for EPA review prior to the initiation of testing. Due to the limited water solubility of some of these

substances and consequent analytical difficulties, some modification of the protocols may be necessary. These modifications will be agreed upon between EPA and the Company.

2. Information on inhalation toxicology if the substances were to be sprayed by commercial or consumer applicants. This could include a 90-day Inhalation study in rats with a 60-day holding period (OPPTS Guideline 870.3465 or OECD 413) or other relevant information.

CONSENT ORDER

I. SCOPE OF APPLICABILITY AND EXEMPTIONS

(a) Scope. The requirements of this Order apply to all commercial manufacturing, processing, distribution in commerce, use and disposal of the chemical substances, [

] CAS Registry Number: [ ] (P-06-388); [

] CAS Registry Number: [ ] (P-06-389); and [

] CAS Registry Number: [ ] (P-06-390) (the "PMN substances") in the United States by [ ] ("the Company"), except to the extent that those activities are exempted by paragraph (b).

(b) Exemptions. Manufacturing of the PMN substances is exempt from the requirements of this Order (except the requirements in the Record keeping and Successor Liability Upon Transfer Of Consent Order sections) only to the extent that (1) these activities are conducted in full

compliance with all applicable requirements of the following exemptions, and (2) such compliance is documented by appropriate record keeping as required in the Record keeping section of this Order.

(1) Export. Until the Company begins commercial manufacture of the PMN substances for use in the United States, the requirements of this Order do not apply to manufacture, processing or distribution in commerce of the PMN substances solely for export in accordance with TSCA §12(a) and (b), 40 CFR 720.3(s) and 40 CFR Part 707. However, once the Company begins to manufacture the PMN substances for use in the United States, no further activity by the Company involving the PMN substances is exempt as "solely for export" even if some amount of the PMN substances is later exported. At that point, the requirements of this Order apply to all activities associated with the PMN substances while in the territory of the United States. Prior to leaving U.S. territory, even those quantities or batches of the PMN substances that are destined for export are subject to terms of the Order, and count towards any production volume test triggers in the Testing section of this Order.

(2) Research & Development (R&D). The requirements of this Order do not apply to manufacturing, processing, distribution in commerce, use and disposal of the PMN substances in small quantities solely for research and development in accordance with TSCA §5(h)(3), 40 CFR 720.3(cc), and 40 CFR 720.36. The requirements of this Order also do not apply to manufacturing, processing, distribution in commerce, use and disposal of the PMN substances when manufactured solely for non-commercial research and development per 40 CFR 720.30(i) and TSCA §5(i).

(3) Byproducts. The requirements of this Order do not apply to the PMN substances when they are produced, without separate commercial intent, only as a "byproduct" as defined at

40 CFR 720.3(d) and in compliance with 40 CFR 720.30(g).

(4) No Separate Commercial Purpose. The requirements of this Order do not apply to the PMN substances when they are manufactured, pursuant to any of the exemptions in 40 CFR 720.30(h), with no commercial purpose separate from the substance, mixture, or article of which they are a part.

(5) Imported Articles. The requirements of this Order do not apply to the PMN substances when they are imported as part of an "article" as defined at 40 CFR 720.3(c) and in compliance with 40 CFR 720.22(b)(1).

(c) Automatic Sunset. If the Company has obtained for the PMN substances a Test Market Exemption (TME) under TSCA §5(h)(1) and 40 CFR 720.38 or a Low Volume Exemption (LVE) or Low Release and Exposure Exemption (LoREX) under TSCA §5(h)(4) and 40 CFR 723.50(c)(1) and (2) respectively, any such exemption is automatically rendered null and void as of the effective date of this Consent Order.

II. TERMS OF MANUFACTURE, IMPORT, PROCESSING, DISTRIBUTION IN COMMERCE, USE, AND DISPOSAL PENDING SUBMISSION AND EVALUATION OF INFORMATION

PROHIBITION

The Company is prohibited from manufacturing the PMN substances in the United States,

for any nonexempt commercial purpose, pending the development of information necessary for a reasoned evaluation of the human health and environmental effects of the substances, and the completion of EPA's review of, and regulatory action based on, that information, in accordance with the conditions described in this Order.

MANUFACTURING

(a)(1) Prohibition. The Company shall not cause, encourage, or suggest the manufacture or import of the PMN substances by any other person.

(2) Sunset Following SNUR. Subparagraph (a)(1) shall expire 75 days after promulgation of a final significant new use rule ("SNUR") governing the PMN substances under section 5(a)(2) of TSCA unless the Company is notified on or before that day of an action in a Federal Court seeking judicial review of the SNUR. If the Company is so notified, subparagraph (a)(1) shall not expire until EPA notifies the Company in writing that all Federal Court actions involving the SNUR have been resolved and the validity of the SNUR affirmed.

(3) Notice of SNUR. When EPA promulgates a final SNUR for the PMN substances and subparagraph (a)(1) expires in accordance with subparagraph (a)(2), the Company shall notify each person whom it causes, encourages or suggests to manufacture or import the PMN substance of the existence of the SNUR.

TESTING

(a) Section 8(e) Reporting. Reports of information on the PMN substances which reasonably supports the conclusion that the PMN substance presents a substantial risk of injury to health or

the environment, which is required to be reported under EPA's section 8(e) policy statement at 43 Federal Register 11110 (March 16, 1978) as amended at 52 Federal Register 20083 (May 29, 1987), shall reference the appropriate PMN identification number for this substance and contain a statement that the substance is subject to this Consent Order. Additional information regarding section 8(e) reporting requirements can be found in the reporting guide referenced at 56 Federal Register 28458 (June 20, 1991).

(b) Notice of Study Scheduling. The Company shall notify, in writing, the EPA Laboratory Data Integrity Branch (2225A), Office of Enforcement and Compliance Assurance, U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, D.C. 20460, of the following information within 10 days of scheduling any study required to be performed pursuant to this Order, or within 15 days after the effective date of this Order, whichever is later:

(1) The date when the study is scheduled to commence;

(2) The name and address of the laboratory which will conduct the study; and

(3) The name and telephone number of a person at the Company or the laboratory whom EPA may contact regarding the study.

(4) The appropriate PMN identification number for each substance and a statement that the substance is subject to this Consent Order.

(c) Good Laboratory Practice Standards and Test Protocols. Each study required to be performed pursuant to this Order must be conducted according to TSCA Good Laboratory Practice Standards at 4O CFR Part 792 and using methodologies generally accepted in the relevant scientific community at the time the study is initiated. Before starting to conduct any

study, the Company must obtain approval of test protocols from EPA by submitting written protocols. EPA will respond to the Company within 4 weeks of receiving the written protocols. Published test guidelines specified in paragraph (d) provide general guidance for development of test protocols, but are not themselves acceptable protocols. Approval of the test protocol does not mean pre-acceptance of test results.

(d) Triggered Testing Requirements. (i) The Company is prohibited from manufacturing or importing the PMN substances beyond an aggregate manufacture and import volume of [ ] kilograms for all three PMN substances combined ("the production limit"), unless the Company conducts the following studies on the PMN substance described in P-06-390 and submits final reports and underlying data in accordance with the conditions specified in this Testing section.

Study	Guideline
Modified Semi-Continuous Activated Sludge (SCAS) with Analysis for degradation products	OPPTS 835.5045 or OECD 302A
UV Visible Light absorption	OPPTS 830.7050, OECD 101
Direct photolysis, if wavelengths Greater than 290nm are absorbed in the previous test	OPPTS 835.2210
Photolysis on soil-- Phototransformation of Chemicals on Soil Surfaces-2 soils	Draft OECD guideline Jan. 2002
Indirect photolysis screening test (Sunlight photolysis in waters Containing dissolved organic carbon)	OPPTS 835.5270

Hydrolysis as a function of pH	OECD 111
Aerobic and Anaerobic Transformation In Aquatic Sediment Systems	OECD 308
Anaerobic Biodegradability of Organic Compounds in Digested Sludge	OECD 311

(ii) Chemical composition of the substance to be tested must be fully characterized. For polymers, characterization includes all information required on pages 5 and 6 of the PMN form, except that data on residuals are only required for fluorinated substances. Special characterization for unique properties of interest to EPA, which may include information claimed as Confidential Business Information (CBI), must be confirmed either through experimental determination or through the Company certification that the express conditions used to manufacture the PMN substances are comparable to cited literature references (and they must be cited), that produce the unique properties of interest. Although EPA understands that complete mass balance may not be achievable for these substances, the Company shall attempt mass balance to the greatest extent practicable, and residuals and impurities analogous to those known to occur in the C8 series must be investigated. EPA prefers that the Company test the commercial substance.

(iii) The Company must test for the following analytes in the Biodegradation tests (OECD 308, OECD 311, and OPPTS 835.5045 or OECD 302A): C6FMA (monomer): CAS No. 2144-53-8; 6-2 carboxylic acid: CAS No. 53826-12-3; 6-2 unsaturated carboxylic acid: CAS No. 161094-75-3; 6-2 alcohol: CAS No. 647-42-7, C6 acid (PFHxA): CAS No. 307-24-4; 5-2 sec.–alcohol: No CAS number, and 5-3 acid: No CAS number.

Because the environmental fate pathway for photolysis and hydrolysis may be different than biodegradation, the Company must test for the following analytes: Hydrolysis test–6:2

telomer alcohol, CAS number: 647-42-7; Photolysis tests–identify the major fluorinated fragments and volatiles including 6:2 telomer alcohol; 6:2 carboxylic acid, tridecafluoro-1-octene (CF3(CF2)5CH=CH2), and tridecafluoroheptanoic acid (CF3(CF2)5CO2H).

(e) Test Reports. The Company shall: (1) conduct each study in good faith, with due care, and in a scientifically valid manner; (2) promptly furnish to EPA the results of any interim phase of each study; and (3) submit, in triplicate (with an additional sanitized copy, if confidential business information is involved), the final report of each study and all underlying data ("the report and data") to EPA no later than 14 weeks prior to exceeding the applicable production limit. The final report shall contain the contents specified in 40 CFR 792.185. Underlying data shall be submitted to EPA in accordance with the applicable "Reporting", "Data and Reporting", and "Test Report" subparagraphs in the applicable test guidelines. However, for purposes of this Consent Order, the word "should" in those subparagraphs shall be interpreted to mean "shall" to make clear that the submission of such information is mandatory. EPA will require the submission of raw data such as slides and laboratory notebooks only if EPA finds, on the basis of professional judgment, that an adequate evaluation of the study cannot take place in the absence of these items.

(f) Testing Waivers. The Company is not required to conduct a study specified in paragraph (d) of this Testing section if notified in writing by EPA that it is unnecessary to conduct that study.

(g) Equivocal Data. If EPA finds that the data generated by a study are scientifically equivocal, the Company may continue to manufacture and import the PMN substances beyond the

applicable production limit. To seek relief from any other restrictions of this Order, the Company may make a second attempt to obtain unequivocal data by reconducting the study under the conditions specified in paragraphs (b), (c), and (e)(1) and (2). The testing requirements may be modified, as necessary to permit a reasoned evaluation of the risks presented by the PMN substances, only by mutual consent of EPA and the Company.

(h) EPA Determination of Invalid Data.

(1) Except as described in subparagraph (h)(2), if, within 6 weeks of EPA's receipt of a test report and data, the Company receives written notice that EPA finds that the data generated by a study are scientifically invalid, the Company is prohibited from further manufacture and import of the PMN substances beyond the applicable production limit.

(2) The Company may continue to manufacture and import the PMN substances beyond the applicable production limit only if so notified, in writing, by EPA in response to the Company's compliance with either of the following subparagraphs (h)(2)(i) or (h)(2)(ii).

(i) The Company may reconduct the study in compliance with paragraphs (b), (c), and (e)(1) and (2). If there is sufficient time to reconduct the study and submit the report and data to EPA at least 14 weeks before exceeding the production limit as required by subparagraph (e)(3), the Company shall comply with subparagraph (e)(3). If there is insufficient time for the Company to comply with subparagraph (e)(3), the Company may exceed the production limit and shall submit the report and data in triplicate to EPA within a reasonable period of time, all as specified by EPA in the notice described in subparagraph (h)(1). EPA will respond to the Company, in writing, within 6 weeks of receiving the Company's report and data.

(ii) The Company may, within 4 weeks of receiving from EPA the notice

described in subparagraph (h)(1), submit to EPA a written report refuting EPA's finding. EPA will respond to the Company, in writing, within 4 weeks of receiving the Company's report.

(i) Company Determination of Invalid Data.

(1) Except as described in subparagraph (i)(2), if the Company becomes aware that circumstances clearly beyond the control of the Company or laboratory will prevent, or have prevented, development of scientifically valid data under the conditions specified in paragraphs (c) and (e), the Company remains prohibited from further manufacture and import of the PMN substances beyond the applicable production limit.

(2) The Company may submit to EPA, within 2 weeks of first becoming aware of such circumstances, a written statement explaining why circumstances clearly beyond the control of the Company or laboratory will cause or have caused development of scientifically invalid data. EPA will notify the Company of its response, in writing, within 4 weeks of receiving the Company's report. EPA's written response may either:

(i) allow the Company to continue to manufacture and import the PMN substances beyond the applicable production limit, or

(ii) require the Company to continue to conduct, or to reconduct, the study in compliance with paragraphs (b), (c), and (e)(1) and (2). If there is sufficient time to conduct or reconduct the study and submit the report and data to EPA at least 14 weeks before exceeding the production limit as required by subparagraph (e)(3), the Company shall comply with subparagraph (e)(3). If there is insufficient time for the Company to comply with subparagraph (e)(3), the Company may exceed the production limit and shall submit the report and data in triplicate to EPA within a reasonable period of time, all as specified by EPA in the notice

described in subparagraph (i)(2). EPA will respond to the Company, in writing, within 6 weeks of receiving the Company's report and data, as to whether the Company may continue to manufacture and import beyond the applicable production limit.

(j) Unreasonable Risk.

(1) EPA may notify the Company in writing that EPA finds that the data generated by a study are scientifically valid and unequivocal and indicate that, despite the terms of this Order, the PMN substance will or may present an unreasonable risk of injury to human health or the environment. EPA's notice may specify that the Company undertake certain actions concerning further testing, manufacture, import, processing, distribution, use and/or disposal of the PMN substance to mitigate exposures to or to better characterize the risks presented by the PMN substance. Within 2 weeks from receipt of such a notice, the Company must cease all manufacture, import, processing, distribution, use and disposal of the PMN substance, unless either:

(2) within 2 weeks from receipt of the notice described in subparagraph (j)(1), the Company complies with such requirements as EPA's notice specifies; or

(3) within 4 weeks from receipt of the notice described in subparagraph (j)(1), the Company submits to EPA a written report refuting EPA's finding and/or the appropriateness of any additional requirements imposed by EPA. The Company may continue to manufacture, import, process, distribute, use and dispose of the PMN substance in accordance with the terms of this Order pending EPA's response to the Company's written report. EPA will respond to the Company, in writing, within 4 weeks of receiving the Company's report. Within 2 weeks of receipt of EPA's written response, the Company shall comply with any requirements imposed by

EPA's response or cease all manufacture, import, processing, distribution, use and disposal of the PMN substance.

(k) Other Requirements. Regardless of the satisfaction of any other conditions in this Testing section, the Company must continue to obey all the terms of this Consent Order until otherwise notified in writing by EPA. The Company may, based upon submitted test data or other relevant information, petition EPA to modify or revoke provisions of this Consent Order pursuant to Part IV. of this Consent Order.

RISK NOTIFICATION

(a) If as a result of the test data required under the terms of this Order, the Company becomes aware that the PMN substance may present a risk of injury to human health (or is so notified by EPA), the Company must incorporate this new information, and any information on methods for protecting against such risk, into a Material Safety Data Sheet ("MSDS"), as described in 40 CFR section 721.72(c), within 90 days from the time the Company becomes aware of the new information. If the PMN substances are not being manufactured, imported, processed, or used in the Company's workplace, the Company must add the new information to an MSDS before the PMN substance is reintroduced into the workplace.

(b) The Company must ensure that persons who will receive the PMN substances from the Company, or who have received the PMN substances from the Company within 5 years from the date the Company becomes aware of the new information described in paragraph (a) of this section, are provided an MSDS containing the information required under paragraph (a) within

90 days from the time the Company becomes aware of the new information.

III. RECORDKEEPING

(a) Records. The Company shall maintain the following records until 5 years after the date they are created and shall make them available for inspection and copying by EPA in accordance with section 11 of TSCA:

(1) Exemptions. Records documenting that the PMN substances did in fact qualify for any one or more of the exemptions described in Section I, Paragraph (b) of this Order. Such records must satisfy all the statutory and regulatory recordkeeping requirements applicable to the exemption being claimed by the Company. Any amounts or batches of the PMN substances eligible for the Export exemption in Section I, Paragraph (b)(3) of this Order, are exempt from all the requirements in this Recordkeeping section, if the Company maintains, for 5 years from the date of their creation, copies of the export label and export notice to EPA, required by TSCA sections 12(a)(1)(B) and 12(b), respectively. Any amounts or batches of the PMN substances eligible for the Research and Development exemption in Section I, Paragraph (b)(4) of this Order, are exempt from all the requirements in this Recordkeeping section, if the Company maintains, for 5 years from the date of their creation, the records required by 40 CFR 720.78(b). For any amounts or batches of the PMN substances claimed to be eligible for any other exemption described in Section I, Paragraph (b) of this Order, the Company shall keep records demonstrating qualification for that exemption as well as the records specified in paragraphs (2) and (3) below, but is exempt from the other record keeping requirements in this Record keeping section;

(2) Records documenting the manufacture and importation volume of the PMN

substances and the corresponding dates of manufacture and import;

(3) Records documenting the names and addresses (including shipment destination address, if different) of all persons outside the site of manufacture or import to whom the Company directly sells or transfers the PMN substances, the date of each sale or transfer, and the quantity of the substance sold or transferred on such date;

(4) Records documenting the address of all sites of manufacture, import, processing, and use;

(5) Copies of material safety data sheets required by the Risk Notification section of this Order;

(6) Copies of any Transfer Documents and notices required by the Successor Liability section of this Order, if applicable; and

(7) The Company shall keep a copy of this Order at each of its sites where the PMN substances are manufactured, imported, processed, or used.

(b) Applicability. The provisions of this Record keeping Section are applicable only to activities of the Company and its Contract Manufacturer, if applicable, and not to activities of the Company's customers.

(c) OMB Control Number. Under the Paperwork Reduction Act and its regulations at 5 CFR Part 1320, particularly 5 CFR 1320.5(b), the Company is not required to respond to this "collection of information" unless this Order displays a currently valid control number from the Office of Management and Budget (OMB), and EPA so informs the Company. The "collection of information" required in this TSCA §5(e) Consent Orders has been approved under currently

valid **OMB Control Number 2070-0012.**

IV. REQUESTS FOR PRE-INSPECTION INFORMATION

(a) EPA's Request for Information. Pursuant to section 11 of TSCA and 40 CFR 720.122, EPA may ocassionally conduct on-site compliance inspections of Company facilities and conveyances associated with the PMN substances. To facilitate such inspections, EPA personnel may contact the Company in advance to request information pertinent to the scheduling and conduct of such inspections. Such requests may be written or oral. The types of information that EPA may request may include, but are not limited to, the following:

(i) Expected dates and times when the PMN substances will be in production within the subsequent 12 months;

(ii) Current workshift schedules for workers who are involved in activities associated with the PMN substance and may reasonably be exposed to the PMN substances;

(iii) Current job titles or categories for workers who are involved in activities associated with the PMN substance and may reasonably be exposed to the PMN substances;

(iv) Existing exposure monitoring data for workers who are involved in activities associated with the PMN substances and may reasonably be exposed to the PMN substances;

(v) Records required by the Record keeping section of this Order; and/or

(vi) Any other information reasonably related to determining compliance with this Order or conducting an inspection for that purpose.

(b) Company's Response. The Company shall respond to such requests within a reasonable period of time, but in no event later than 30 days after receiving EPA's request. When requested

in writing by EPA, the Company's response shall be in writing. To the extent the information is known to or reasonably ascertainable to the Company at the time of the request, the Company's response shall demonstrate a good faith effort to provide reasonably accurate and detailed answers to all of EPA's requests.

(c) Confidential Business Information. Any Confidential Business Information (CBI) that the Company submits to EPA pursuant to paragraph (b) shall be protected in accordance with §14 of TSCA and 40 CFR Part 2.

V. SUCCESSOR LIABILITY UPON TRANSFER OF CONSENT ORDER

(a) Scope. This section sets forth the procedures by which the Company's rights and obligations under this Order may be transferred when the Company transfers its interests in the PMN substance, including the right to manufacture the PMN substances, to another person outside the Company (the "Successor in Interest").

(b) Relation of Transfer Date to Notice of Commencement ("NOC").

(1) Before NOC. If the transfer from the Company to the Successor in Interest is effective before EPA receives a notice of commencement of manufacture or import ("NOC") for the PMN substances from the Company pursuant to 40 CFR 720.102, the Successor in Interest must submit new PMNs to EPA and comply fully with Section 5(a)(1) of TSCA and 40 CFR part 720 before commencing manufacture or import of the PMN substance.

(2) After NOC. If the transfer from the Company to the Successor in Interest is effective

after EPA receives a NOC, the Successor in Interest shall comply with the terms of this Order and shall not be required to submit new PMNs to EPA.

(c) Definitions. The following definitions apply to this Successor Liability section of the Order:

(1) "Successor in Interest" means a person outside the Company who has acquired the Company's full interest in the rights to manufacture the PMN substances, including all ownership rights and legal liabilities, through a transfer document signed by the Company, as transferor, and the Successor in Interest, as transferee. The term excludes persons who acquire less than the full interest of the Company in the PMN substances, such as a licensee who has acquired a limited license to the patent or manufacturing rights associated with the PMN substances. A Successor in Interest must be incorporated, licensed, or doing business in the United States in accordance with 40 CFR 720.22(3).

(2) "Transfer Document" means the legal instrument(s) used to convey the interests in the PMN substance, including the right to manufacture the PMN substances, from the Company to the Successor in Interest.

(d) Notices.

(1) Notice to Successor in Interest. On or before the effective date of the transfer, the Company shall provide to the Successor in Interest, by registered mail, a copy of the Consent Order and the "Notice of Transfer" document which is incorporated by reference as Attachment C to this Order.

(2) Notice to EPA. Within 10 business days of the effective date of the transfer, the Company shall, by registered mail, submit the fully executed Notice of Transfer document to:

U.S. Environmental Protection Agency, New Chemicals Branch (7405), 1200 Pennsylvania Avenue, N.W., Washington, D.C. 20460.

(3) Transfer Document. Copies of the Transfer Document must be maintained by the Successor in Interest at its principal place of business, and at all sites where the PMN substance is manufactured or imported. Copies of the Transfer Document must also be made available for inspection pursuant to Section 11 of TSCA, must state the effective date and time of transfer, and must contain provisions which expressly transfer liability for the PMN substances under the terms of this Order from the Company to the Successor in Interest.

(e) Liability.

(1) The Company shall be liable for compliance with the requirements of this Order until the effective date and time of the transfer described above.

(2) The Successor in Interest shall be liable for compliance with the requirements of this Order effective as of the date and time of transfer.

(3) Nothing in this section shall be construed to prohibit the Agency from taking enforcement action against the Company after the effective date of the transfer for actions taken, or omissions made, during the time in which the Company manufactured, processed, used, distributed in commerce, or disposed of the PMN substance pursuant to the terms of this Consent Order.

(f) Obligations to Submit Test Data under Consent Order. If paragraph (d) of the Testing section of this Consent Order requires the Company to submit test data to EPA at a specified production volume ("test trigger"), the aggregate volume of the PMN substances manufactured and imported

by the Company up to the date of transfer shall count towards the test trigger applicable to the Successor in Interest.

VI. MODIFICATION AND REVOCATION OF CONSENT ORDER

The Company may petition EPA at any time, based upon new information on the health effects of, or human exposure to, the PMN substances, to modify or revoke substantive provisions of this Order. The exposures and risks identified by EPA during its review of the PMN substances and the information EPA determined to be necessary to evaluate those exposures and risks are described in the preamble to this Order. However, in determining whether to amend or revoke this Order, EPA will consider all relevant information available at the time the Agency makes that determination, including, where appropriate, any reassessment of the test data or other information that supports the findings in this Order, an examination of new test data or other information or analysis, and any other relevant information.

EPA will issue a modification or revocation if EPA determines that the activities proposed therein will not present an unreasonable risk of injury to health or the environment and will not result in significant or substantial human exposure or substantial environmental release in the absence of data sufficient to permit a reasoned evaluation of the health or environmental effects of the PMN substances.

In addition, the Company may petition EPA at any time to make other modifications to the language of this Order. EPA will issue such a modification if EPA determines that the modification is useful, appropriate, and consistent with the structure and intent of this Order as issued.

VII. EFFECT OF CONSENT ORDER

By consenting to the entry of this Order, the Company waives its rights to file objections to this Order pursuant to section 5(e)(1)(C) of TSCA, to receive service of this Order no later than 45 days before the end of the review period pursuant to section 5(e)(1)(B) of TSCA, and to challenge the validity of this Order in any subsequent action. Consenting to the entry of this Order, and agreeing to be bound by its terms, do not constitute an admission by the Company as to, the facts or conclusions underlying the Agency's determinations in this proceeding. This waiver does not affect any other rights that the Company may have under TSCA.

6/29/06
Date

/s/
Jim Willis, Director
Chemical Control Division
Office of Pollution Prevention and Toxics

7/03/06
Date

/s/
Name:

Title:

Company: [ ]

ATTACHMENT A

DEFINITIONS

[Note: The attached Order may not contain some of the terms defined below.]

"Chemical name" means the scientific designation of a chemical substance in accordance with the nomenclature system developed by the International Union of Pure and Applied Chemistry or the Chemical Abstracts Service's rules of nomenclature, or a name which will clearly identify a chemical substance for the purpose of conducting a hazard evaluation.

"Company" means the person or persons subject to this Order.

"Commercial use" means the use of a chemical substance or any mixture containing the chemical substance in a commercial enterprise providing saleable goods or a service to consumers (e.g., a commercial dry cleaning establishment or painting contractor).

"Common name" means any designation or identification such as code name, code number, trade name, brand name, or generic chemical name used to identify a chemical substance other than by its chemical name.

"Consumer" means a private individual who uses a chemical substance or any product containing the chemical substance in or around a permanent or temporary household or residence, during recreation, or for any personal use or enjoyment.

"Consumer product" means a chemical substance that is directly, or as part of a mixture, sold or made available to consumers for their use in or around a permanent or temporary household or residence, in or around a school, or in recreation.

"Container" means any bag, barrel, bottle, box, can, cylinder, drum, reaction vessel, storage tank, or the like that contains a hazardous chemical. For purposes of this section, pipes or piping systems, and engines, fuel tanks, or other operating systems in a vehicle, are not considered to be containers.

"Contract Manufacturer" means a person, outside the Company, who is authorized to manufacture and import the PMN substance under the conditions specified in Part II. of this Consent Order and in the Consent Order for Contract Manufacturer.

"Identity" means any chemical or common name used to identify a chemical substance or a mixture containing that substance.

"Immediate use." A chemical substance is for the "immediate use" of a person if it is under the control of, and used only by, the person who transferred it from a labeled container and will only be used by that person within the work shift in which it is transferred from the labelled container.

"Manufacturing stream" means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of manufacture, including the cleaning of equipment.

"MSDS" means material safety data sheet, the written listing of data for the chemical substance.

"NIOSH" means the National Institute for Occupational Safety and Health of the U.S. Department of Health and Human Services.

"Non-enclosed process" means any equipment system (such as an open-top reactor, storage tank, or mixing vessel) in which a chemical substance is manufactured, processed, or otherwise used where significant direct contact of the bulk chemical substance and the workplace air may occur.

"Non-industrial use" means use other than at a facility where chemical substances or mixtures are manufactured, imported, or processed.

"PMN substance" means the chemical substance (see TSCA s. 3(2)) described in the Premanufacture notice submitted by the Company relevant to this Order.

"Process stream" means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of processing, including the cleaning of equipment.

"Scientifically invalid" means any significant departure from the EPA-approved protocol or the Good Laboratory Practice Standards at 40 CFR Part 792 without prior or subsequent Agency approval that prevents a reasoned evaluation of the health or environmental effects of the PMN substance.

"Scientifically equivocal data" means data which, although developed in apparent conformity with the Good Laboratory Practice Standards and EPA-approved protocols, are inconclusive, internally inconsistent, or otherwise insufficient to permit a reasoned evaluation of the potential risk of injury to human health or the environment of the PMN substance.

"Sealed container" means a closed container that is physically and chemically suitable for long-term containment of the PMN substance, and from which there will be no human exposure to, nor environmental release of, the PMN substance during transport and storage.
"Use stream" means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of industrial, commercial, or consumer use.

"Workplace" means an establishment at one geographic location containing one or more work areas.

ATTACHMENT B

NOTICE OF TRANSFER
OF
TOXIC SUBSTANCES CONTROL ACT
SECTION 5(e) CONSENT ORDER

_____ _____
Company (Transferor) PMN Number

1. Transfer of Manufacture Rights. Effective on _____, the Company did sell or otherwise transfer to _____, ("Successor in Interest") the rights and liabilities associated with manufacture of the above-referenced chemical substance, which was the subject of a premanufacture notice (PMN) and is governed by a Consent Order issued by the U.S. Environmental Protection Agency (EPA) under the authority of §5(e) of the Toxic Substances Control Act (TSCA, 15 U.S.C. §2604(e)).

2. Assumption of Liability. The Successor in Interest hereby certifies that, as of the effective date of transfer, all actions or omissions governed by the applicable Consent Order limiting manufacture, processing, use, distribution in commerce and disposal of the PMN substance, shall be the responsibility of the Successor in Interest. Successor in Interest also certifies that it is incorporated, licensed, or doing business in the United States in accordance with 40 CFR 720.22(3).

3. Confidential Business Information. The Successor in Interest hereby:

___ reasserts,

___ relinquishes, or

___ modifies

all Confidential Business Information (CBI) claims made by the Company, pursuant to Section 14 of TSCA and 40 CFR part 2, for the PMN substance(s). Where "reasserts" or "relinquishes" is indicated, that designation shall be deemed to apply to all such claims. Where "modifies" is indicated, such modification shall be explained in detail in an attachment to this Notice of Transfer. Information which has been previously disclosed to the public (e.g., a chemical identity that was not claimed as CBI by the original submitter) would not subsequently be eligible for confidential treatment under this Notice of Transfer.

TOXIC SUBSTANCES CONTROL ACT
SECTION 5(e) CONSENT ORDER

NOTICE OF TRANSFER
(continued)

Company (Transferor)	PMN Number
Signature of Authorized Official	Date
Printed Name of Authorized Official	
Title of Authorized Official	

Successor in Interest

Signature of Authorized Official	Date
Printed Name of Authorized Official	
Title of Authorized Official	
Address	
City, State, Zip Code	

TOXIC SUBSTANCES CONTROL ACT
SECTION 5(e) CONSENT ORDER

NOTICE OF TRANSFER
(continued)

_____
Successor's Technical Contact

_____
Address

_____
City, State, Zip Code

_____
Phone